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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,535	02/20/2001	Guy Rousseau	VANM198.001A	7462

7590

06/19/2003

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 06/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/763,535

Examiner

Daniel M Sullivan

Applicant(s)

ROUSSEAU ET AL.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133)
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 07 May 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 4-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 August 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

This Non-Final Office Action is a response to the "Amendment and Response..." filed 7 May 2002 (Paper No. 9) filed in reply to the Non-Final Office Action mailed 3 January 2002 (Paper No. 8). Claims 1-9 were considered in Paper No. 8. Claims 2 and 3 were canceled and claims 1, 4 and 7 were amended in Paper No. 9. Claims 1 and 4-9 are pending and under consideration.

#### *Response to Amendment*

Rejection of claims 2 and 3 is rendered moot by cancellation of the claims.

#### Drawings

The formal drawings filed 6 August 2002 are objected to for the reasons indicated on the attached PTO-948. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### INFORMATION ON HOW TO EFFECT DRAWING CHANGES

#### 1. **Correction of Informalities -- 37 CFR 1.85**

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing

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the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

**2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.**

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

**Timing of Corrections**

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Claim Rejections - 35 USC § 112

Claims 1 and 4-9 stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement for reasons of record in Paper No. 8 and herein below in the "Response to Arguments".

Claim Rejections - 35 USC § 102

Rejection of claim 1 under 35 USC § 102(b) as anticipated by Lemaigre *et al.* (1996) *Proc. Natl. Acad. Sci. USA* 93:9460-9464 is withdrawn.

Rejection of claims 4 and 5 under 35 USC § 102(b) as anticipated by Jacquemin *et al.* (1999) *J. Biol. Chem.* 274:2665-2671 is withdrawn.

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Rejection of claim 6 under 35 USC § 102(b) as anticipated by Krolewski (1998) WO 98 23780 is withdrawn.

New grounds for rejection are set forth herein below.

### ***Response to Arguments***

#### Claim Rejections - 35 USC § 112

Claims 1 and 4-9 were rejected under 35 U.S.C. §112, first paragraph, as lacking enablement for pharmaceutical compositions comprising onecut polypeptides, nucleic acids encoding said onecut polypeptides or cells expressing said onecut polypeptides, or for therapeutic methods comprising administering the claimed pharmaceutical compositions.

In response to the rejection, Applicant points out that the specification describes methods by which polynucleotides of the claimed invention may be administered to a patient or to cell lines of a patient via *ex vivo* treatment. Applicant points out that specification discloses methods for using the presently claimed pharmaceutical composition in cell therapy and further describes the components of the pharmaceutical composition. Applicant argues that the specification has enabled the therapeutic component of the claimed pharmaceutical composition and asserts that one of skill in the art would be capable of making and using the presently claimed invention by suiting the presently claimed invention to their specific application conditions.

These arguments have been fully considered but are not found persuasive. In the rejection of record, the Examiner cites several teachings from the relevant art which indicate that obtaining a therapeutic effect using gene therapy techniques available in the art at the time of

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filing was highly unpredictable. The teachings from the specification cited by Applicant in the response are merely general statements that the pharmaceutical compositions will be used to treat various conditions and non-specific descriptions of methods of administering pharmaceutical compositions which are well known to the skilled artisan. These teachings do not address the grounds set forth for the enablement rejection which are, "the art recognized unpredictability of achieving therapeutic levels of gene expression following direct or indirect administration of nucleic acid vectors, and the unpredictability of extending the results of animal systems to humans, the lack of guidance provided by the specification for the parameters affecting delivery and expression of therapeutic amounts of DNA into the cells, the lack of guidance concerning the treatment of diabetes, cancer and Waardenburg syndrome using the polynucleotide of the instant invention" (Paper No. 8, page 7). Because the methods set forth in the instant application provide no guidance that would enable the skilled artisan to overcome the art recognized barriers to obtaining therapeutic effect using compositions and methods such as those claimed in the instant application, the skilled artisan would not be able to use the claimed invention for the purposes contemplated in the instant disclosure without engaging in undue experimentation. Therefore, the claims stand rejected as lacking an enabling disclosure.

### ***New Grounds***

#### Claim Objections

Claim 8 is objected to because of the following informalities: The claim depends from canceled claims 2 and 3. Appropriate correction is required.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim reads on a method wherein cells are transformed by treating said cells with a pharmaceutical composition comprising an element selected from the group consisting of an OC-2 polypeptide or a cell line transformed with a vector comprising an OC-2 polypeptide encoding nucleic acid. Transformation is understood in the art to constitute genetic modification. It is unclear how a cell can be transformed by treating said cell with an OC-2 polypeptide or a cell line transformed with a vector comprising an OC-2 polypeptide encoding nucleic acid.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by Jacquemin *et al.* (1999) *J. Biol. Chem.* 274:2665-2671.

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As pointed out in the previous Office Action at page 9, Jacquemin *et al.* discloses the nucleotides sequence of human OC-2 and the OC-3, which anticipate the present claims 1, 3 and 5. In response to the previous rejection, Applicant argues that Jacquemin *et al.* does not qualify as prior art because the filing date of the Belgian application to which the instant application claims priority predates the publication date of Jacquemin *et al.* However, Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15. This rejection can be overcome by providing a certified translation of the priority document.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


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dms

June 16, 2003



JAMES KETTER  
PRIMARY EXAMINER